

Quantitative assessment of the risk of ovine Johne's disease in sheep flocks

Final Report

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Abbreviations and Acronyms

<i>AWI</i>	Australian Wool Innovation Limited
<i>CT</i>	Check tested status
<i>CZ</i>	Control Zone
<i>IFP</i>	Infected flock profile (negative flock test in an infected flock)
<i>NA</i>	Nil Assured status
<i>NOJDP</i>	National Ovine Johne's Disease Control and Evaluation Program
<i>OJD</i>	Ovine Johne's disease
<i>PZ</i>	Protected Zone
<i>SheepMAP</i>	The Australian Johne's Disease Market Assurance Program for Sheep
<i>SU</i>	Suspect status
<i>RD</i>	Restricted status (2 negative tests in an infected flock)
<i>RZ</i>	Residual Zone
<i>US</i>	Under surveillance status

Glossary

<i>Flock-prevalence</i>	Proportion of flocks in a defined region or group of flocks that are infected
<i>Relative risk</i>	The ratio of disease incidence in individuals exposed to a hypothesised risk or mitigating factor to the incidence in those not exposed
<i>Within-flock prevalence</i>	Proportion of animals in an infected flock that are infected

1 Executive Summary

The current rules governing movement of sheep between zones on account of ovine Johne's disease (OJD), and between flocks with different SheepMAP status, are based largely on qualitative and imprecise judgments of relative risk. This is particularly true in regard to flocks that vaccinate or undertake other practices to reduce the likelihood of being infected and the prevalence if they are infected. This study was undertaken to explore the feasibility of a sheep trading system based on quantitative assessment of the risk of OJD transmission. Such a system would allow the development of movement restrictions that are more objective and more transparent than has previously been possible. Such a system would also allow more flexibility in the management of OJD-risk, and could be less restrictive on flocks that are taking positive steps to control or prevent the disease. It would also allow individual flocks to better manage their OJD-risk when trading within or between zones.

A novel approach was used to develop a classification system for sheep flocks based on the OJD-risk that they pose. Using this approach, flocks were classified on the basis of location (State and zone) and infection status, including market assured flocks and infected flocks with varying levels of prevalence and negative testing. A quantitative risk-model was developed to estimate the mean and upper 95% limit of risk for flocks in each category (*risk-index*). The *risk-index* for a flock-category was calculated as the product of the probability that the flock is infected and the likely within-flock prevalence of infection if it is infected, and represents the likelihood that a single randomly selected sheep from flocks in the category would be infected. This *risk-index* was then converted to an integer *risk-score* between 0 (lowest risk) and 13 (highest risk), with each point difference in score representing a doubling (or halving) of the risk compared to the adjacent category. The table below shows a summary of the flock-categories considered and their *risk-scores*.

Although this *risk-score* provides a simple and objective assessment of flock-risk for OJD, there was considerable uncertainty associated with the final values, such that the upper 95% limit for each category was generally 1 – 2 points higher than the mean. Therefore, it may be appropriate to manually adjust some categories to ensure that like categories are grouped together. Similarly it would be appropriate to set a maximum value for the *risk-score* (for example 10 or 12), and adjust the individual values as necessary to fit within this limit.

To increase the flexibility and usefulness of this approach, a simple method for adjusting *risk-scores* was also developed, based on the expected change in risk associated with specific flock-characteristics or practices, such as vaccination, biosecurity measures, negative surveillance results, etc. Using this approach, a doubling (halving of risk) results in a one point addition (deduction) to the score, with points being additive. For example, if ongoing vaccination of lambs over a 3-6 year period is assumed to halve the prevalence in a flock, there is a corresponding halving in the flock-risk, and therefore a one-point deduction from the *risk-score*.

Additional factors that are likely to affect flock-risk, and that should be considered for inclusion in a flock's final *risk-score* were:

- Abattoir surveillance results in the last 2 years
- Number of infected neighbours
- Purchasing history for the previous five years
- Biosecurity measures implemented
- Breed of sheep
- Grazing management practices implemented
- Vaccination
- Sheep risk – are particular groups (eg hoggets) a higher risk?

Table of flock categories by zone, State and flock status, and their corresponding risk-scores

Zone or flock type	Flock category	Risk-score
Protected Zone	MN3	0
Control Zone	MN3	1
Protected Zone	MN2	1
Protected Zone	Queensland unrestricted	2
Protected Zone	Check tested	2
Residual Zone	MN3	3
Control Zone	MN2	3
Protected Zone	South Australia unrestricted	3
Protected Zone	Tasmania unrestricted	4
Residual Zone	MN2	4
Protected Zone	New South Wales unrestricted	5
Control Zone	MN1	6
Protected Zone	Victoria unrestricted	6
Residual Zone	MN1	7
Control Zone	Check tested	8
Infected flocks	3 negative tests	8
Control Zone	Unrestricted	9
Infected flocks	2 negative tests	9
Residual Zone	Check tested	9
Infected flocks	1 negative test	9
Infected flocks	Low prevalence	10
Residual Zone	Unrestricted	12
Infected flocks	High prevalence	13

Simulation modelling suggested that for the Residual Zone a high coverage with vaccination is essential for effective control, with movement restrictions providing additional benefit if vaccination coverage is <100%. For the Protected Zone, a reduction in the level of ongoing introduction of infection from other zones and effective surveillance for early identification and vaccination of infected flocks are essential for effective control. Ring vaccination and/or quarantine of infected flocks and adoption of risk-based trading within and between zones instead of the current inter-zone movement restrictions would provide added control.

Although the main important factors affecting OJD-risk have been identified and quantitative values suggested for them in this report, a full analysis for each of these factors, singly or in combination has not been undertaken. However, using the method

described above, it is possible to estimate appropriate relative risks for each category of these factors, and adjust the *risk-scores* accordingly. Before this approach is taken further, there needs to be a more detailed consideration of these factors at a national level and agreement to appropriate risk-categories and relative risks for each factor, as well as agreement on appropriate surveillance and control strategies for each zone.

2 Introduction

2.1 Background to this report

The NOJDP uses two complementary systems to minimise the risk of OJD transmission between flocks: zoning and the Sheep Market Assurance Program (SheepMAP).

Zoning allows the national flock to be segmented according to risk of infectivity, which in turn permits some targeting in surveillance and control programs. SheepMAP allows producers to buy or sell sheep with some degree of confidence about the risk associated with individual flocks, and supports trade between high and low prevalence zones.

The two systems have shortcomings. The specific rules governing trade in and out of zones, and between flocks with different SheepMAP status, are based largely on qualitative and imprecise judgments of relative risk. This is particularly true in regard to flocks that vaccinate. Producer groups are critical of the lack of the opportunities for flocks labelled 'infected' or 'suspect' to continue their businesses, despite untested flocks facing no such constraints.

Australian Wool Innovation Limited (AWI) and Animal Health Australia commissioned this study to explore the feasibility of a sheep trading system based on quantitative assessment of the risk of OJD transmission. Such a system would:

- Allow a greater range of variables to be taken into account when assessing risk of infectivity of a flock: for example, number and age of vaccinations; results of all testing, not just isolated positives; purchases of sheep; and other risk factors, as these are identified and quantified by research.
- Offer a more finely calibrated range of status categories, so that producers can take small steps and yet make concrete progress towards expanding their trading options.
- Provide sheep traders with a best-available, quantitative estimate of the risk of purchasing sheep from a flock with a given profile.
- Provide incentives for producers to ascertain the status of their flock or to undertake vaccination, because 'test-positive' does not represent financial disaster for the business, and is likely to be only a matter of degrees from 'status unknown and no vaccination'.

Such a system of risk profiling could be entirely market-based, with voluntary (or compulsory) vendor declarations, and sanctions based only on common law provisions related to inadequate disclosure. Alternatively, this approach could be supported by a regulatory overlay to allow regional containment or eradication objectives to be met. These policies would be more objective and more transparent than currently possible.

2.2 Terms of Reference

The terms of reference for this project were as specified in the contract with AWI, and are repeated below.

The Consultant is required to:

1. *Identify and list the key pieces of information (variables) available and useful in estimating the risk of infectivity of a flock.*
2. *Quantify the risk associated with each variable and reasonable combination of variables. This would include, but not necessarily be confined to:*
 - *Test status: Monitored Negative 1, MN2, MN3 under SheepMAP; status unknown, check test, suspect, infected; zone; frequency and type of testing;*
 - *Vaccination: yes/no, time since vaccination commenced;*
 - *Introductions: status of source flock, number of sheep introduced, time since introduction.*
 - *Flocks following approved 'pathways'.*
3. *Evaluate options for risk-based classification of individual flocks, using either a series of discrete risk categories, or a points-based system.*
4. *In consultation with a reference group, identify a range of intervention strategies for each zone (surveillance and control) and quantify the outcomes of each.*

2.3 Study team

The study was undertaken by Dr Evan Sergeant from AusVet Animal Health Services. The reference group referred to in point 4 of the terms of reference comprised Drs Bruce Allworth, Tony Higgs and Barbara Moloney. This group was consulted throughout the project to ensure that the approach taken and assumptions used were acceptable and reasonable.

2.4 Methods

This project was undertaken in consultation with the reference group described above by email correspondence and teleconferences, as necessary. The following approach was used for this study:

1. A *risk-index* value was defined that can be calculated for any property according to specific characteristics of the property, including the State and zone in which it is situated and the regulatory or SheepMAP status applicable to the property.
2. Factors which may affect this *risk-index* (risk or mitigating factors) were identified and evaluated, and the likely magnitude of any effect assessed.
3. A stochastic risk-model was developed using an Excel® spreadsheet and @Risk® simulation software to allow calculation of the risk-index for flocks categorised by State, zone, status and other risk-factors.
4. Quantitative risk estimates for each combination of State, zone and status were converted to an integer risk-scale from 0 to 13, and a method was developed for adjusting a flock's *risk-score* according to the assumed relative risk of any of the various risk or mitigating factors that may apply.

3 Risk-assessment model

3.1 Risk of OJD infection of individual flocks

Johne's disease spreads primarily through contact with infected faeces, and spread between properties may occur through either the planned movement of sheep between properties (sale/purchase or agistment), or from local spread via movement of sheep or faeces between adjoining properties or over commonly used ground.

Therefore, the risk of infectivity of a flock can be considered in two separate contexts:

1. The risk that it poses to neighbouring flocks and other flocks with which it has indirect contact, such as through common use of roads or facilities; and
2. The risk that it poses to other flocks which purchase sheep from the flock or which have other direct contact such as through agistment of sheep.

For this project, 'risk' was defined as the likelihood (probability) of an individual or group of sheep being infected. It does not consider the likelihood of infection establishing on another property, the volume of trade between properties or regions, or the potential consequences if transmission and establishment of infection do occur.

Ultimately, the risk associated with any individual flock is determined by the probability that the flock is infected, and the probability that individuals within the flock are infected (within-flock prevalence). This risk may then be modified by measures taken to reduce these probabilities (e.g. biosecurity, vaccination) and to reduce the risk of spread to other flocks (e.g. barriers to local spread, movement controls) or by factors which increase these probabilities. For producers purchasing from another flock, the risk of infection also increases with consignment size.

3.2 Identified risk factors

Important factors which may affect the OJD-risk for an individual flock include:

- The probability that the flock is infected (estimated as the prevalence of infected flocks, among flocks of similar type or status in the region or zone of origin);
- The prevalence of infection in the flock (if it is known to be infected), or in epidemiologically similar infected flocks;
- Past purchasing history (volume and source of purchased sheep);
- OJD infection status of neighbours;
- Duration of infection and action taken to control infection on neighbouring properties;
- Any biosecurity measures implemented to prevent the introduction of infection;
- The length of time that biosecurity measures have been in place;
- Breed of sheep (breed has been suggested as possibly affecting disease risk, based on anecdotal reports of higher mortality rates in Merinos than in British Breeds, but has still to be confirmed as a true risk-factor);
- Any measures in place to reduce the prevalence of infection (eg vaccination, grazing management); and

- The length of time that control measures have been in place.

Additional factors which affect the risk of exposure of other flocks include:

- Any measures in place to prevent lateral spread of infection to neighbouring and other properties;
- Conditions in place for the movement of sheep from the property;
- The prevalence of infection in sale sheep (usually hoggets) or other sub-populations in the flock, or in epidemiologically similar flocks; and
- Consignment size for sale or agistment sheep.

For producers purchasing sheep, the risk of infection in a group of purchased sheep increases with the number of sheep in the consignment. However, because this assessment is directed mainly at assessment and categorisation of the risk of infection at the flock level, consignment size was not specifically considered. Although consignment size was not specifically included, its consideration is implicit in the consideration of purchasing history of rams only compared to purchasing replacement sheep. Consignment size could also be considered as another risk-factor and added to the model as such, with appropriate categorisation and relative risks.

Based on the above factors, specific risk or mitigating factors were included in the analysis, as shown in Figure 1 and Table 1. In the long term vaccination is likely to reduce the likelihood that a flock is infected (by elimination of infection in some flocks), as well as reducing the prevalence within the infected flock. However, because the former is a longer-term effect, and is still not confirmed as occurring, it has not been included in the model at this stage. As more data becomes available it may be appropriate to include this as an additional effect.

Figure 1. Hypothesised risk and mitigating factors for OJD flock-risk.

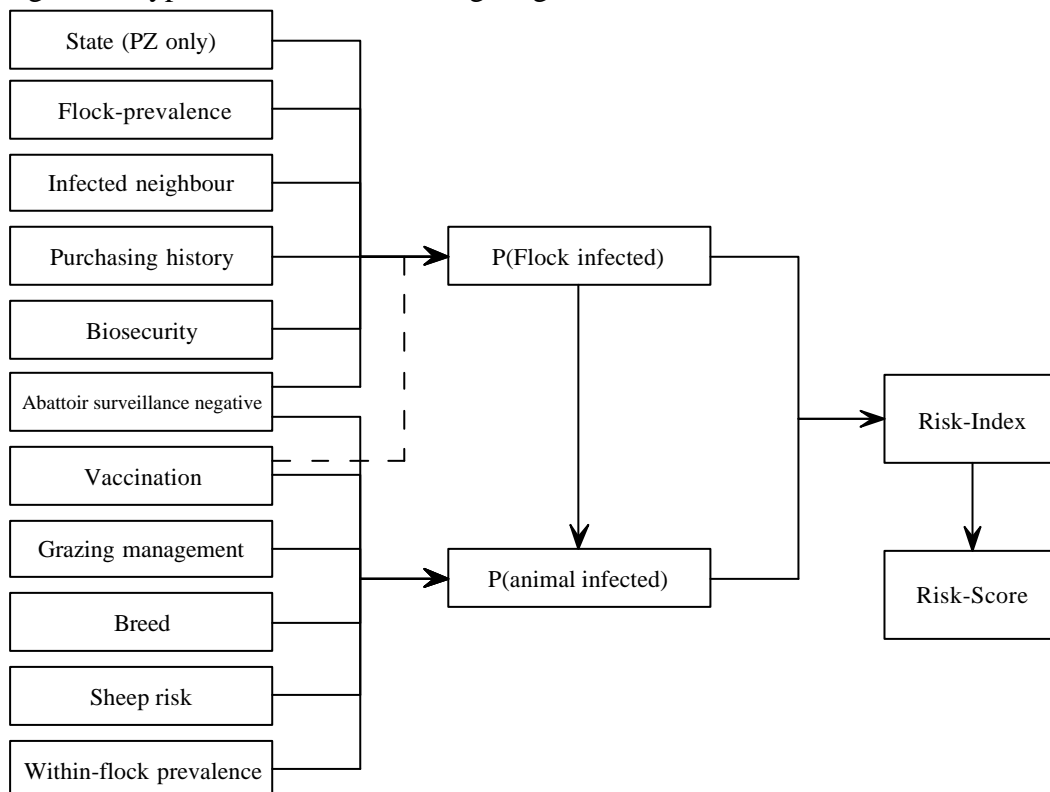


Table 1. Assumed risk and mitigating factors for the risk of OJD in a flock

Factor	Description
State (STATE)	State in which flock is located (Protected Zone only)
Flock prevalence (FP)	Estimated percentage of flocks that are infected
Within-flock prevalence (WFP)	Estimated percentage of infected adult sheep in infected flocks
Abattoir surveillance (AS)	Effect of negative abattoir surveillance results on likely FP and/or WFP
Infected neighbours (NBRS)	Increase in FP associated with infected neighbours
Purchasing history (PH)	Increase in FP associated with purchasing sheep from lower status zones or flocks
Biosecurity (BIO)	Reduction in FP associated with implementation of biosecurity measures
Breed (BRD)	Effect of breed on WFP
Grazing management (GM)	Effect of grazing management practices on WFP
Vaccination (VACC)	Effect of vaccination on WFP
Sheep risk (SR)	Effect of sheep type on WFP

3.3 Calculating a *risk-index*

For each scenario considered, a *risk-index* for the scenario was calculated. Risk-indices were calculated on a flock basis only, rather than on a geographic basis, because there was insufficient data on sheep movements and trading patterns to estimate risks on a regional or group basis, and because the intention was to group flocks according to the risk they pose, based on geographic, management and disease-related factors.

The basic *risk-index* for a flock or group of flocks sharing similar characteristics was calculated as:

$$\text{Risk-index} = \text{FP} * \text{WFP}, \quad (1)$$

where FP and WFP are the assumed values for flock-prevalence and within-flock prevalence, respectively. For this calculation assumed values for FP and WFP were specified according to the zone and status of the flock(s).

Factors other than FP and WFP were then incorporated in the model as relative-risk values, which were used to multiply the assumed (prior) values of FP or WFP to obtain an adjusted (posterior) value reflecting the change in risk associated with the particular factor. Thus the final *risk-index* for a flock was calculated as:

$$P(\text{Flock infected}) = \text{FP} * \text{AS}(\text{flock}) * \text{NBRS} * \text{PH} * \text{BIO} * \text{STATE} \quad (2)$$

$$P(\text{Animal infected} | \text{Flock infected}) = \text{WFP} * \text{AS}(\text{animal}) * \text{VACC} * \text{GM} * \text{BRD} * \text{SR} \quad (3)$$

$$\text{Risk-index} = P(\text{Flock infected}) * P(\text{Animal infected} | \text{Flock infected}) \quad (4)$$

This approach depends on two important assumptions:

- Putative risk or mitigating factors are independent of each other; and

- The factors apply equally across States, zones and for varying flock-status.

Given the nature of the factors considered, and the variation between the various flock categories, these assumptions are unlikely to be met and the resulting risk-estimates will be biased, with the nature and extent of the bias depending on the type and degree to which the assumptions were violated. However, there was insufficient data on which to base stratum-specific estimates, and the resulting model would have been excessively complicated. Therefore, the approach outlined above was considered to be the best option available in the circumstances.

3.4 Risk-model

A simulation model was developed using an Excel[®] spreadsheet and @Risk[®] simulation software based on Figure 1. Risk factors as listed in Table 1 were incorporated as parameters in the final model, using probability distributions, as described below. For each iteration of the model, the *risk-index* is equivalent to the risk of infection for a single, randomly selected adult sheep from a randomly selected flock, and was calculated using formulae 2, 3 and 4. For each iteration, new values were selected from each of the input distributions, and a new value for the *risk-index* was generated. The model was run for 5,000 iterations for each scenario, to generate a distribution of *risk-index* values. For each scenario, the mean and 95th percentile of the output distribution were reported.

3.5 Parameter values

Beta distributions were used for FP and WFP because this is a commonly used distribution for expressing uncertainty about a proportion (such as prevalence) and is easily defined from the mode and 5th or 95th percentiles. Pert distributions were used for relative risk values because this is a useful distribution for expressing uncertainty about a value, based on minimum, most likely and maximum values.

Assumed most likely values and 95% limits for input distributions for FP and WFP for each scenario are shown in Table 2, along with alpha and beta values that best fit the assumed values.

Table 2. Prior estimates of mode and 95% limit for FP and WFP for various combinations of zone and status, and alpha and beta values for the input distributions for each parameter.

Zone/Flock	Status/ Prevalence	Description	Parameter	Most likely value	Upper/ lower 95% limit	Alpha	Beta
Protected zone							
	Unrestricted	MN1 equivalent	FP	0.1%	0.5%	2	920
	Unrestricted		WFP	1.0%	5.0%	1.9	88
	CT ^a	Unrestricted + check test	FP	0.5%	1.0%	6.7	1138
	CT		WFP	1.0%	2.0%	6.6	560
	MN2	Unrestricted + sample test	FP	0.2%	0.5%	5	1838

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MN2		WFP	0.7%	2.0%	3.4	338
MN3	MN2 + test	FP	0.1%	0.50%	1.9	920
MN3		WFP	0.7%	1.5%	5.7	664
Control zone						
Unrestricted	NA	FP	10.0%	20.0%	5.7	43
Unrestricted		WFP	2.0%	10.0%	1.8	42
CT	Unrestricted + check test	FP	7.5%	15.0%	6	62
CT		WFP	2.2%	5.4%	4.2	143
MN1	Unrestricted + sample test	FP	5.0%	10.0%	6.2	100
MN1		WFP	1.0%	2.7%	3.6	260
MN2	MN1 + sample test	FP	0.70%	1.5%	5.7	664
MN2		WFP	0.80%	1.7%	5.8	593
MN3	MN2 + sample test	FP	0.15%	0.5%	2.8	1190
MN3		WFP	0.80%	1.4%	9.8	1090
Residual zone						
Unrestricted	NA, SU, US	FP	40.0%	55.0%	12.7	19
Unrestricted		WFP	5.0%	30.0%	1.5	10.8
CT	Unrestricted + check test	FP	15.0%	30.0%	5	24
CT		WFP	3.3%	8.0%	4.1	93
MN1	Unrestricted + sample test	FP	10.0%	20.0%	5.7	43
MN1		WFP	1.2%	4.0%	2.7	143
MN2	MN1 + sample test	FP	2.00%	4.0%	6.5	272
MN2		WFP	1.0%	2.0%	6.6	560
MN3	MN2 + sample test	FP	0.60%	1.20%	6.7	945
MN3		WFP	1.0%	1.6%	13.4	1233
Infected flocks						
HP ^b	>=3/7 pools positive?	FP	100.0%	100.0%	10000	1
HP		WFP	10.0%	30.0%	2.5	15
LP ^c	1-2/7 pools positive	FP	100.0%	100.0%	10000	1
LP		WFP	1.5%	3.0%	6.5	370
IFP ^d	1 negative tests	FP	95.0%	80.0%	21	2
IFP		WFP	0.49%	2.1%	2.3	260
RD ^e	2 negative tests	FP	80.0%	50.0%	7.5	2.6
RD		WFP	0.49%	2.1%	2.3	260
US ^f	3 negative tests	FP	50.0%	30.0%	8	8
US		WFP	0.49%	2.1%	2.3	260

^a CT = check tested, ^b HP = high prevalence, ^c LP = low prevalence, ^d IFP = infected flock profile (negative), ^e RD = restricted (2 negative tests), ^f US = under surveillance (3 negative tests).

Suggested categories and minimum, most likely and maximum values for each of the risk-factors are listed in Table 3. Generally, these values are highly uncertain and quite subjective, and may need considerable debate and further research to determine the most appropriate values.

The values for these parameters were derived in consultation with the reference group, as follows:

- Minimum, most likely and maximum values for the relative risk of a flock being infected according to State within the PZ were based on previous estimates of flock-prevalence by State and region, calculated from abattoir surveillance data up to 31 December 2001 (see Appendix 1. Sergeant, in press). Assumed values for FP for unrestricted flocks from Queensland were as shown in Table 2 for the 'PZ – unrestricted' category and most likely and maximum values for relative risk for other states were as shown in Table 3, calculated as the ratio between the median and upper 95% limit for prevalence estimates and the median estimate of FP for Qld. The minimum relative risk for all States was assumed to be one;
- For negative abattoir surveillance, @Risk simulation was used to simulate the results of abattoir surveillance in the PZ, CZ and RZ. The output of these simulations were used to define the minimum, most likely and maximum values for the expected reduction in FP and WFP in negative flocks (see Appendix 2);
- The probability that a flock is infected increases with the number of known infected neighbours. The relative risk values used were derived from previous estimates of the risk from infected neighbours (Sergeant and Baldock, 2002), adjusted downwards to account for the likely bias in these estimates;
- Values for Purchasing history, Biosecurity, Grazing management and Breed were determined by agreement with the reference group, because there was no data available on which to base realistic estimates;
- Values for vaccination were based on the results of simulation modelling as shown in Appendix 3; and
- Values for estimated Sheep-risk were based on the results of simulation modelling as shown in Appendix 3.

Table 3. Factors increasing or decreasing the risk of OJD, and the estimated minimum, most likely and maximum values for the relative risk for each level of the factors.

Factor	Level	Minimum	Most likely	Maximum
Factors affecting FP				
State (PZ only)	Queensland	1	1	1
	South Australia	1	2	4
	Tasmania	1	3	9
	New South Wales	1	10	17
	Victoria	1	18	35
AS negative (number of sheep negative in the last 2 years)	<=50	1	1	1
	51-500	0.1	0.3	0.4
	501-1000	0.05	0.1	0.2
	>1000	0.02	0.05	0.1
Infected neighbours	None	1	1	1
	1	2	4	6
	>=2	6	8	12
Purchasing history (in the last 5 yrs)	Purchase from same or higher status only	1	1	1

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	Rams only, next lower zone or status	1	1.5	2
	Replacement sheep, next lower zone or status	1.5	2	3
	Any sheep from infected flock	4	8	12
Biosecurity	Nil	1	1	1
	Level 1 e.g. No co-grazing	0.6	0.7	0.8
	Level 2 e.g. Level 1 plus no sharing of facilities	0.4	0.5	0.6
	Level 3 e.g. Level 2 plus double fencing	0.1	0.25	0.4
Factors affecting WFP				
AS negative (number of sheep negative in the last 2 years)	<50	1	1	1
	51-500	0.25	0.5	0.66
	501-1000	0.15	0.3	0.45
	>1000	0.1	0.25	0.35
Breed	Merino	1	1	1
	X-Bred	1.00	1	1.00
	British breed	1.00	1	1.00
Grazing management	Set-stocked sheep	1	1	1
	Cell grazing	1.2	2	3
	Rotate with cattle/crop	0.2	0.5	0.7
	Other?	1.00	1	1.00
Vaccination	<=2 years	1		
	>2 to <6 years	0.2	0.5	0.7
	>=6 years	0.05	0.1	0.3
Sheep risk (hoggets)	Unvaccinated adults	1	1	1
	Vaccinated hoggets	0.5	0.7	1
	Unvaccinated Hoggets	1.6	1.9	2.5

3.6 Initial risk assessment

An initial risk assessment was carried out for flocks categorised according to the following variables:

1. State and Zone of origin
2. Flock status (SheepMAP or regulatory status)
3. Estimated or assumed flock-prevalence
4. Estimated or assumed within-flock prevalence

Specific scenarios assessed included:

Protected zone – Unrestricted (MN1 default) by State, CT, MN2 and MN3

Control zone – Unrestricted (NA), CT and MN1-3

Residual zone – Unrestricted (NA/SU/US), CT and MN1-3

Infected flocks (any zone) – High prevalence, Low prevalence, IFP (infected flock profile – 1 negative test), RD (2 negative tests) and US (3 negative tests)

For this analysis, all other risk or mitigating factors (for example vaccination, biosecurity, abattoir surveillance results, infected neighbours, etc) were assumed to take their reference values, with relative risk =1.

A second analysis was also undertaken for comparison, using the same scenarios, except that the flock was assumed to be vaccinated for 2 – 6 years. Risk estimates were also calculated for the base scenarios using a deterministic model with FP and WFP taking the most likely values as listed for each scenario.

3.7 Calculating a *risk-score*

For each scenario, a *risk-score* was calculated from the mean *risk-index* value as follows

$$\text{Risk-score} = \log_2(\text{risk-index} * 10000)$$

The *risk-score* was rounded to the nearest integer, and a constant (3) added to provide a minimum value of 0. The resulting scale of *risk-scores* was a series of integer values ranging from 0 to 13, with each unit increase (decrease) in score representing a doubling (halving) of the risk compared to the previous category. A \log_2 scale was used to transform the *risk-index* because it provides a better discrimination between categories and allows a meaningful and intuitive interpretation of *risk-score* values than would a simple linear transformation.

Using this scale, it is also possible to adjust the initial *risk-score* for a flock based on State, zone and status for the effects of other risk/mitigating factors by adding or subtracting points on the scale according to the magnitude of the relative risk. For example, vaccination for 3-6 years has a mean relative risk of 0.5, and thus would result in a one-point deduction from the score. Conversely, having one known infected neighbour results in a relative risk of four, equivalent to a two-point addition to the score.

3.8 Results & Discussion

The base risk-estimates ranged from 0 to 13, with a reasonable spread of values in between (Tables 4 and 5). The *risk-scores* for the upper 95th percentile were generally 1 – 2 points higher than the mean, but generally had the same ranking, while vaccination resulted in a one-point reduction in the *risk-score* for all scenarios.

Deterministic estimates were generally similar to their stochastic counterparts, although the ranking changed somewhat. The main categories which changed their ranking with respect to the rest were the Protected Zone unrestricted categories for each State. This occurred because the underlying distribution for FP in Protected Zone that was used in the @Risk model was quite skewed and close to zero, so that the mean of the distribution was approximately twice the value for the mode. This resulted in deterministic estimates (based on the mode) that were downwardly biased compared to

the stochastic estimates, so that the final *risk-score* for these estimates was one point lower, relative to the other categories.

The relative risk values used for each State in the Protected Zone may also be subject to some debate. The values used were based on the best estimates of prevalence available for these States, but may be subject to some bias. Alternative values could be tested if necessary, however, the spread of values across all States provides a good indication of the likely score for alternative relative risk values.

Table 4. Mean and upper 95% values for *risk-index* for various base-scenarios, and for corresponding scenarios assuming vaccination of lambs has been practised for 2 – 6 years, and mean values calculated using a deterministic approach, sorted by *risk-score* for the base scenario

Zone or flock type	State/Status	Base scenario				Vaccination scenario				Deterministic estimates	
		Mean		95%		Mean		95%		Mean	
		<i>Risk-index</i>	<i>Risk-score</i>	<i>Risk-index</i>	<i>Risk-score</i>	<i>Risk-index</i>	<i>Risk-score</i>	<i>Risk-index</i>	<i>Risk-score</i>	<i>Risk-index</i>	<i>Risk-score</i>
PZ ^a	MN3	0.00002	0	0.00005	2	0.00001	-1	0.00002	1	0.00001	-1
CZ ^b	MN3	0.00002	1	0.0000	2	0.00001	0	0.000	1	0.00001	0
PZ	MN2	0.00003	1	0.00007	2	0.00001	0	0.00003	1	0.00001	0
PZ	Qld unrestricted	0.00005	2	0.00014	4	0.00002	1	0.00007	3	0.00001	0
PZ	CT	0.00007	2	0.00014	3	0.00003	1	0.00007	3	0.00005	2
RZ ^c	MN3	0.0001	3	0.0001	3	0.0000	2	0.0001	3	0.00006	2
CZ	MN2	0.00008	3	0.0002	4	0.00004	2	0.000	3	0.00006	2
PZ	SA unrestricted	0.00010	3	0.00032	5	0.00005	2	0.00016	4	0.00002	1
PZ	Tas unrestricted	0.00017	4	0.00056	5	0.00008	3	0.00027	4	0.00003	1
RZ	MN2	0.0003	4	0.0006	5	0.0001	3	0.0003	4	0.00020	4
PZ	NSW unrestricted	0.00044	5	0.00146	7	0.00021	4	0.00072	6	0.00010	3
CZ	MN1	0.00079	6	0.0018	7	0.00038	5	0.001	6	0.00050	5
PZ	Vic unrestricted	0.00082	6	0.00276	8	0.00040	5	0.00135	7	0.00018	4
RZ	MN1	0.0022	7	0.0052	9	0.0010	6	0.0026	8	0.00120	7
CZ	CT	0.00250	8	0.0055	9	0.00121	7	0.003	8	0.00165	7
IN flocks ^d	3 negative tests	0.004	8	0.010	10	0.002	7	0.005	9	0.00247	8
CZ	Unrestricted	0.00477	9	0.0126	10	0.00230	8	0.006	9	0.00200	7
IN flocks	2 negative tests	0.006	9	0.015	10	0.003	8	0.008	9	0.00395	8
RZ	CT	0.0072	9	0.0160	10	0.0035	8	0.0081	9	0.00488	9
IN flocks	1 negative test	0.008	9	0.018	11	0.004	8	0.009	9	0.00469	9
IN flocks	LP	0.017	10	0.030	11	0.008	9	0.015	10	0.01500	10
RZ	Unrestricted	0.0486	12	0.1226	13	0.0235	11	0.0615	12	0.02000	11
IN flocks	HP	0.143	13	0.297	15	0.069	12	0.147	14	0.10000	13

^a PZ = Protected zone, ^b CZ = Control zone, ^c RZ = Residual zone, ^d IN flocks = Infected flocks

Table 5. Mean and upper 95% values for *risk-index* for various base-scenarios, and for corresponding scenarios assuming vaccination of lambs has been practised for 2 – 6 years, and mean values calculated using a deterministic approach, sorted by zone and State/status

Zone or flock type	State/Status	Base scenario				Vaccination scenario				Deterministic estimates	
		Mean		95%		Mean		95%		Mean	
		<i>Risk-index</i>	<i>Risk-score</i>	<i>Risk-index</i>	<i>Risk-score</i>	<i>Risk-index</i>	<i>Risk-score</i>	<i>Risk-index</i>	<i>Risk-score</i>	<i>Risk-index</i>	<i>Risk-score</i>
PZ ^a	Qld unrestricted	0.00005	2	0.00014	4	0.00002	1	0.00007	3	0.00001	0
	SA unrestricted	0.00010	3	0.00032	5	0.00005	2	0.00016	4	0.00002	1
	Tas unrestricted	0.00017	4	0.00056	5	0.00008	3	0.00027	4	0.00003	1
	NSW unrestricted	0.00044	5	0.00146	7	0.00021	4	0.00072	6	0.00010	3
	Vic unrestricted	0.00082	6	0.00276	8	0.00040	5	0.00135	7	0.00018	4
	CT	0.00007	2	0.00014	3	0.00003	1	0.00007	3	0.00005	2
	MN2	0.00003	1	0.00007	2	0.00001	0	0.00003	1	0.00001	0
	MN3	0.00002	0	0.00005	2	0.00001	-1	0.00002	1	0.00001	-1
CZ ^b	Unrestricted	0.00477	9	0.0126	10	0.00230	8	0.006	9	0.00200	7
	CT	0.00250	8	0.0055	9	0.00121	7	0.003	8	0.00165	7
	MN1	0.00079	6	0.0018	7	0.00038	5	0.001	6	0.00050	5
	MN2	0.00008	3	0.0002	4	0.00004	2	0.000	3	0.00006	2
	MN3	0.00002	1	0.0000	2	0.00001	0	0.000	1	0.00001	0
RZ ^c	Unrestricted	0.0486	12	0.1226	13	0.0235	11	0.0615	12	0.02000	11
	CT	0.0072	9	0.0160	10	0.0035	8	0.0081	9	0.00488	9
	MN1	0.0022	7	0.0052	9	0.0010	6	0.0026	8	0.00120	7
	MN2	0.0003	4	0.0006	5	0.0001	3	0.0003	4	0.00020	4
	MN3	0.0001	3	0.0001	3	0.0000	2	0.0001	3	0.00006	2
IN flocks ^d	HP	0.143	13	0.297	15	0.069	12	0.147	14	0.10000	13
	LP	0.017	10	0.030	11	0.008	9	0.015	10	0.01500	10
	1 negative test	0.008	9	0.018	11	0.004	8	0.009	9	0.00469	9
	2 negative tests	0.006	9	0.015	10	0.003	8	0.008	9	0.00395	8
	3 negative tests	0.004	8	0.010	10	0.002	7	0.005	9	0.00247	8

^a PZ = Protected zone, ^b CZ = Control zone, ^c RZ = Residual zone, ^d IN flocks = Infected flocks

4 Risk-based classification options

4.1 Proposed *risk-score* approach

The approach described above provides a useful framework for assessing risk of OJD infection based on flock characteristics, and for comparison of risk between flocks with different characteristics. The integer scale used makes it relatively simple to understand and use, although the number of categories is quite high.

For simplicity it is probably appropriate to cap the scale with a maximum value (for example 10 or 12) and adjust the individual values slightly to ensure appropriate grouping of flocks with similar risk and adequate separation of those with different risks.

Considering the uncertainty about the estimates provided here, manual refinement of the *risk-scores* for individual categories is not unreasonable.

If desired, it would also be possible to further reduce the number of categories by either re-analysing using a different log scale, or simply by amalgamating groups with similar scores. This would result in a loss of discrimination across the spectrum of risk, and would also make the adjustment of *risk-score* for risk/mitigating factors more difficult.

Consignment size is an important determinant of risk when purchasing sheep, although it has not been specifically considered in this analysis. In reality, as the number of sheep in a consignment increases, the risk of infection also increases, in a non-linear fashion (for example, purchasing one sheep from a flock with a *risk-score* of 3 has a risk of about 0.0001 (1 in 10,000) of infection. Purchasing 10 or 100 sheep instead of one increases the risk of infection by 9-fold and 36-fold, respectively). Therefore, when developing a risk-based trading scheme, consignment size should be an important consideration.

Consignment size could also be included in the proposed approach as another risk/mitigating factor, with the consignment-risk calculated by adjustment of the flock-risk. In addition, it is essential to emphasise the importance of consignment size to purchasers, so that they can manage their risk by considering this in their purchasing behaviour.

Although the main important factors affecting OJD-risk have been identified and quantitative values suggested for them, a full analysis for each of these factors, singly or in combination has not been undertaken. However, using the method described above, it is possible to estimate appropriate relative risks for each category of these factors, and adjust the *risk-scores* accordingly. Before this approach is taken further there needs to be a more detailed consideration of these factors at a national level, and agreement to appropriate risk-categories and relative risks for each factor.

4.2 Revised system based on zoning and MAP

An alternative approach to risk-classification would be the development of inter-zone (and perhaps intra-zone) trading restrictions based on MAP status \pm vaccination. Such a system could be similar in many ways to the system proposed above, but would be more restrictive, because it would not include known infected flocks or other risk/mitigating factors that may have an important impact on flock-risk.

4.3 Qualitative risk-assessment system

The beef and dairy industries are currently developing qualitative risk-based trading systems for use in their respective industries. The beef industry approach is still in the early stages of development and is not available for comparison.

The initial version of the dairy industry approach (still under development) is a points-based system, with points allocated for a property's assessed BJD status, biosecurity measures in place and preventive management measures. While similar in concept, this approach is more limited in the number and scope of risk/mitigating factors considered, and the meaning of the final *risk-score* is less intuitive than for the approach proposed above. It is also an additive approach, with points added for actions taken to reduce risk, but not deducted for 'risky' practices or circumstances.

The availability of surveillance data in the sheep industry has supported the approach used in this project. Similar data is not currently available for the cattle industries, and therefore a similar approach to that described for sheep is unlikely to be possible for the beef and dairy industries.

4.4 Fully quantitative system

A fully quantitative system, based on the raw *risk-index* value, or different risk value calculated by alternative means (eg including consignment size) would provide the maximum amount of information to producers on which to base decisions. However, because this approach would provide risk values that may lie anywhere on a continuum of risk, the level of detail and complexity of such a system is likely to preclude its effective uptake by producers. Such a system would also be difficult to implement because of uncertainty about many of the input values, and the inherently qualitative nature of some of the data.

5 Evaluation of possible intervention strategies for Residual and Protected Zones

A simulation model of the regional spread of OJD among flocks was used to simulate the uncontrolled spread of infection and a range of alternative control options for the Residual Zone and for several simulations in the Protected Zone. Because of the artificial nature of this model, the results should be interpreted with some caution, and should not be regarded as accurate predictions of flock-prevalence under the various scenarios. Instead, model output should be regarded as providing a general indication of the expected results, and a comparison of trends between scenarios will be more useful than the actual flock-prevalence values reported.

5.1 Residual Zone

The main assumptions for the Residual Zone simulation were:

- 4,000 properties in the zone, with 10% having no sheep;
- A prevalence at the start of the scenario of ~40% of flocks infected;
- There was no ongoing introduction of infection from outside the zone; and
- Vaccine has a moderate efficacy (60% protection and 40% reduction in progression).

The simulation was run for 5 iterations, each of 20 years duration, for the following scenarios:

Scenario	Description
No control measures implemented (NC)	<ul style="list-style-type: none"> • No surveillance, quarantine or vaccination
Surveillance and quarantine only (SQ)	<ul style="list-style-type: none"> • Random surveillance on 500 flocks/year, 30% of flocks avoid testing, quarantine of detected infected flocks.
Surveillance and quarantine with vaccination (SQV)	<ul style="list-style-type: none"> • Random surveillance on 500 flocks/year, 30% of flocks avoid testing, quarantine and vaccination of detected infected flocks.
MAP only with movement restrictions (MAP)	<ul style="list-style-type: none"> • All purchases from MAP flocks only (\geqMN1), starting in Year 2; and • All flocks undergo MAP testing over first 10 years.
Vaccination only, 70% uptake with movement restrictions (VMR)	<ul style="list-style-type: none"> • All purchases from vaccinated flocks only, starting in Year 2; and • 70% flocks vaccinate from Year 1, infected flocks more likely to vaccinate as mortality rate increases.
High-level surveillance and quarantine only (HSQ)	<ul style="list-style-type: none"> • Random surveillance on 1000 flocks/year, 5% of flocks avoid testing, quarantine of detected infected flocks.
Vaccination only, 70% uptake with no movement restrictions (V no MR)	<ul style="list-style-type: none"> • 70% flocks vaccinate from Year 1, infected flocks more likely to vaccinate as mortality rate increases; and • No movement restrictions.
Blanket vaccination (V100)	<ul style="list-style-type: none"> • Vaccination of all flocks commencing in year 1, with 100% uptake.

Additional scenarios were run for ring vaccination of detected infected flocks and their neighbours, both with and without quarantine of the detected flock (SRV, SQRV, HSRV and HSQRV) and using an assumed low-efficacy vaccine, providing 50% protection of

susceptible sheep and 0% reduction in progression (SQV le, VMR le, V (no MR) le and V100 le).

Results for the Residual Zone simulations are summarised in Figures 2, 3 and 4. Briefly, the NC scenario resulted in a continued rapid rise to >80% over the simulated 20-year period. For the SQ and HSQ scenarios, prevalence continued to rise, but more slowly than for the NC scenario, depending on the level of surveillance. For the MAP scenario, flock prevalence initially declined slightly before starting to increase again towards the end of the simulation. All vaccination scenarios (assuming a moderate-efficacy vaccine) resulted in a progressive decline in prevalence over the 20-year simulation. Restricting purchases to sheep from vaccinated flocks only, with random vaccination of 70% of flocks, resulted in a decline in flock-prevalence from about 40% to 11% after 20 years. This decline was more rapid if the percentage of flocks vaccinating was increased to 100% (7%), and was slower if purchases were not restricted to vaccinating flocks only (20%), or if fewer flocks are vaccinated (results not shown). Flock-prevalence also decreased if vaccination was combined with quarantine of detected infected flocks, particularly if ring vaccination of detected flocks was included. Ring vaccination (with or without quarantine of detected flocks) resulted in about 65 – 70% of flocks vaccinating by year 20.

Use of a low-efficacy vaccine resulted in a slower decline or a moderate increase in flock-prevalence over the 20-year simulation, assuming vaccination of a proportion of flocks at random. Surveillance and quarantine plus vaccination with a low-efficacy vaccine provided only marginally better control than surveillance and quarantine alone.

Figure 2: Mean flock-prevalence for Residual Zone scenarios, assuming a 40% flock-prevalence at the start, a 20-year simulation period and a moderate-efficacy vaccine.

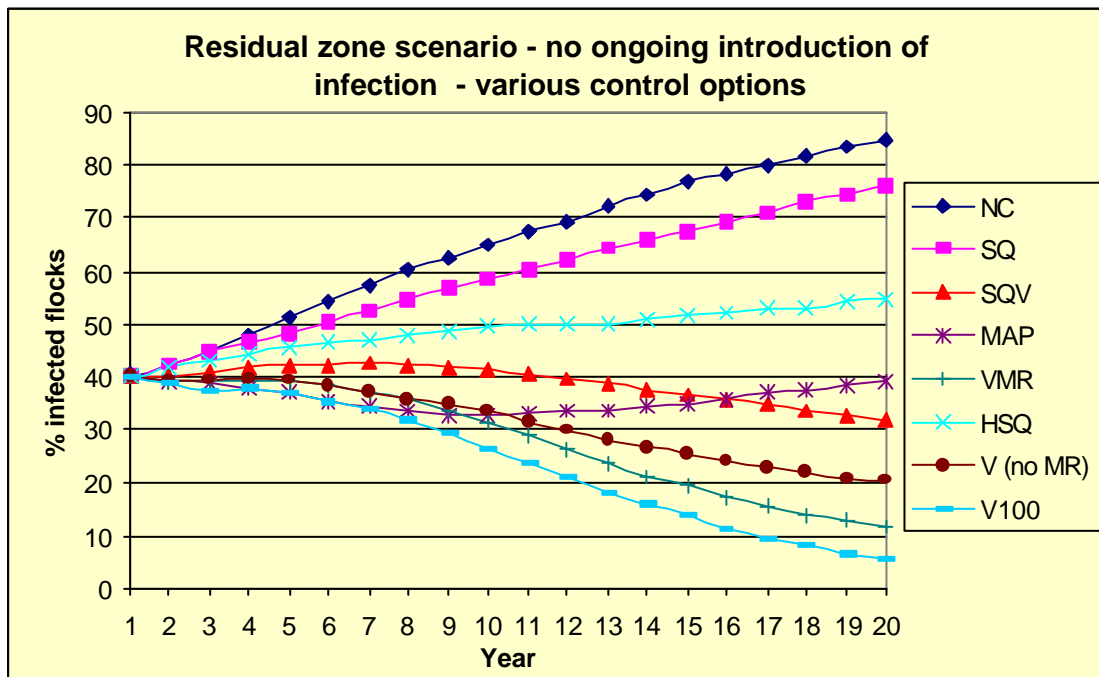


Figure 3: Mean flock-prevalence for Residual Zone scenarios, assuming a 40% flock-prevalence at the start, a 20-year simulation period and a moderate-efficacy vaccine, including ring vaccination of detected infected flocks.

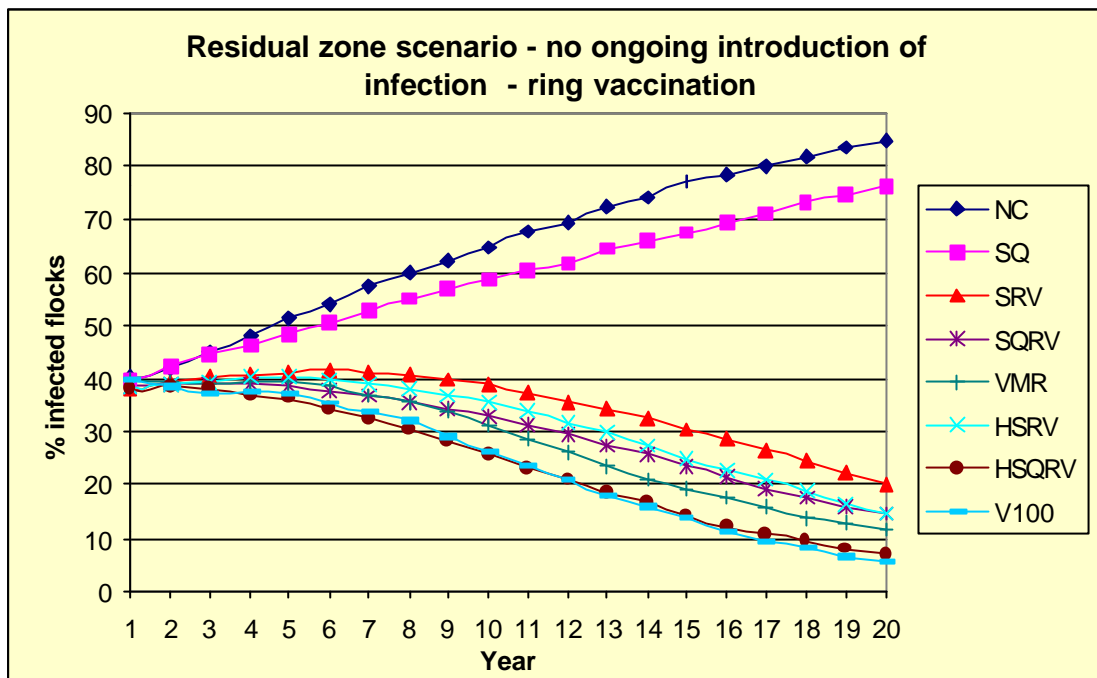
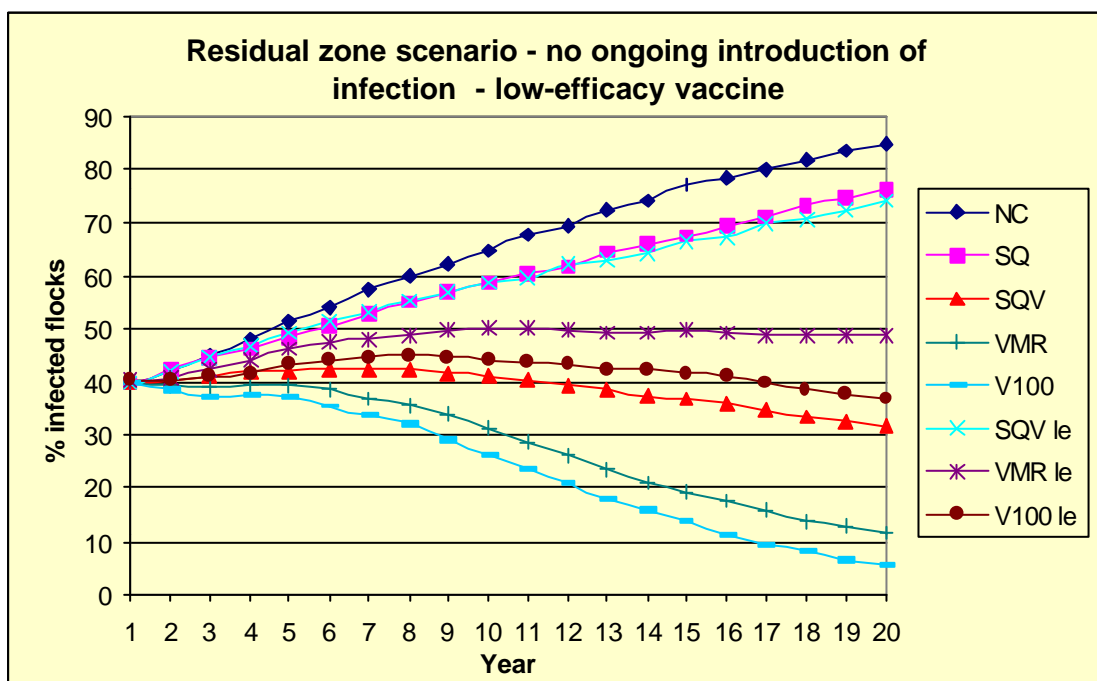


Figure 4: Mean flock-prevalence for Residual Zone scenarios, assuming a 40% flock-prevalence at the start, a 20-year simulation period and a low-efficacy vaccine.



5.2 Protected zone simulations

5.2.1 Closed zone

The main assumptions for the first Protected Zone simulation were:

- Starting prevalence ~0.5%;
- 10,000 properties, 10% no sheep;
- Closed region (no ongoing introduced infection) and;
- Vaccine has a moderate efficacy (60% protection and 40% reduction in progression)

The model was run for 5 iterations, each of 20 years duration, for the following scenarios:

Scenario	Description
No control measures implemented (NC)	<ul style="list-style-type: none"> • No surveillance, quarantine or vaccination
Surveillance and quarantine only (SQ)	<ul style="list-style-type: none"> • Random surveillance on 1000 flocks/year, 30% of flocks avoid testing, quarantine of detected infected flocks.
Surveillance with quarantine and vaccination (SQV)	<ul style="list-style-type: none"> • Random surveillance on 1000 flocks/year, 30% of flocks avoid testing, quarantine and vaccination of detected infected flocks.
Surveillance and vaccination only (SV)	<ul style="list-style-type: none"> • Random surveillance on 1000 flocks/year, 30% of flocks avoid testing, vaccination of detected infected flocks.
High-level surveillance and quarantine only (HSQ)	<ul style="list-style-type: none"> • Random surveillance on 2000 flocks/year, 10% of flocks avoid testing, quarantine of detected infected flocks.
High-level surveillance with vaccination only (HSV)	<ul style="list-style-type: none"> • Random surveillance on 2000 flocks/year, 10% of flocks avoid testing, vaccination of detected infected flocks.
Vaccination only, 20% uptake with no movement restrictions (V)	<ul style="list-style-type: none"> • 20% flocks vaccinate from Year 1 (randomly selected in year 1), infected flocks more likely to vaccinate as mortality rate increases.

The four scenarios that included vaccination were also repeated using an assumed low-efficacy vaccine providing a 50% protection of susceptible sheep and 0% reduction in progression (SQVle, SVle, HSVle and Vle).

Results for the first Protected Zone simulation are summarised in Figures 5 and 6. Flock-prevalence increased progressively under the NC scenario, reaching 54% after 40 years. The SQ, HSQ and V scenarios all provided reasonable control, with flock-prevalence increasing slowly to 4 – 6% after 40 years. All other scenarios considered (assuming a moderate vaccine efficacy) provided a high level of control, with flock-prevalence remaining $\leq 1\%$ after 40 years. Ring vaccination would provide even better control than shown here. If vaccine efficacy was assumed to be low, flock-prevalence under all vaccination strategies increased much more rapidly, reaching 38%, 15% and 12% for the Vle, SVle and HSVle simulations, respectively. Quarantine of detected infected flocks made little difference to final flock-prevalence if vaccine was assumed to be moderately effective. In contrast, quarantine provided a much higher level of control when combined with vaccination if vaccination efficacy was assumed to be low.

Figure 5: Mean flock-prevalence for Protected Zone scenarios, assuming a 0.5% flock-prevalence at the start, no ongoing introductions of infection, a 40-year simulation period and a moderate-efficacy vaccine.

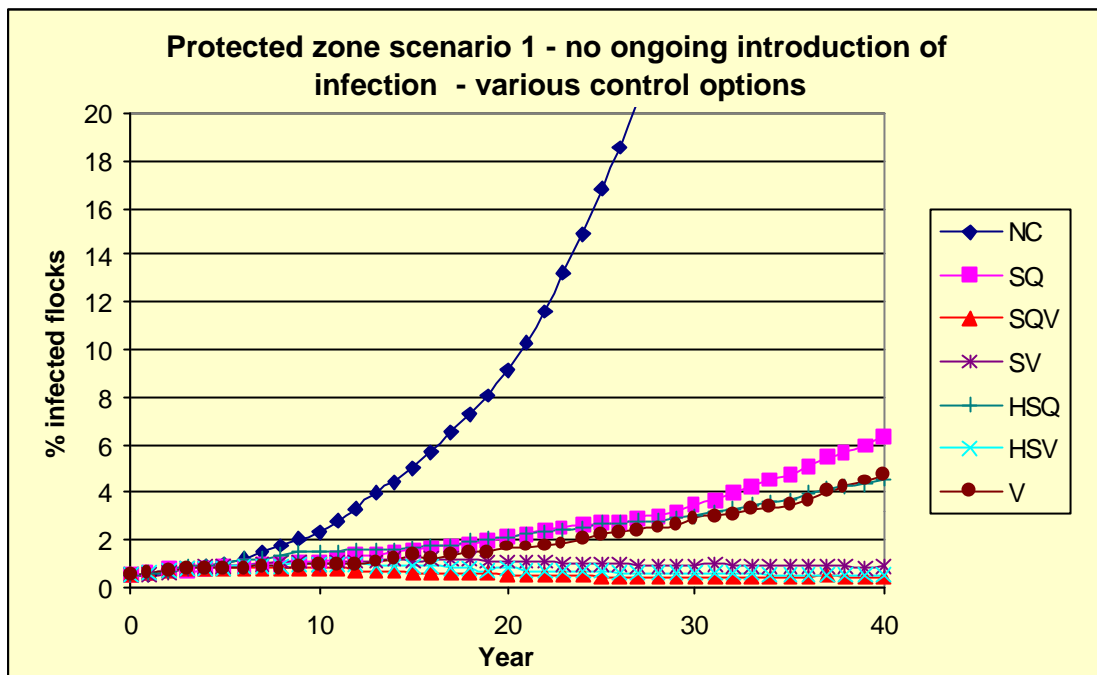
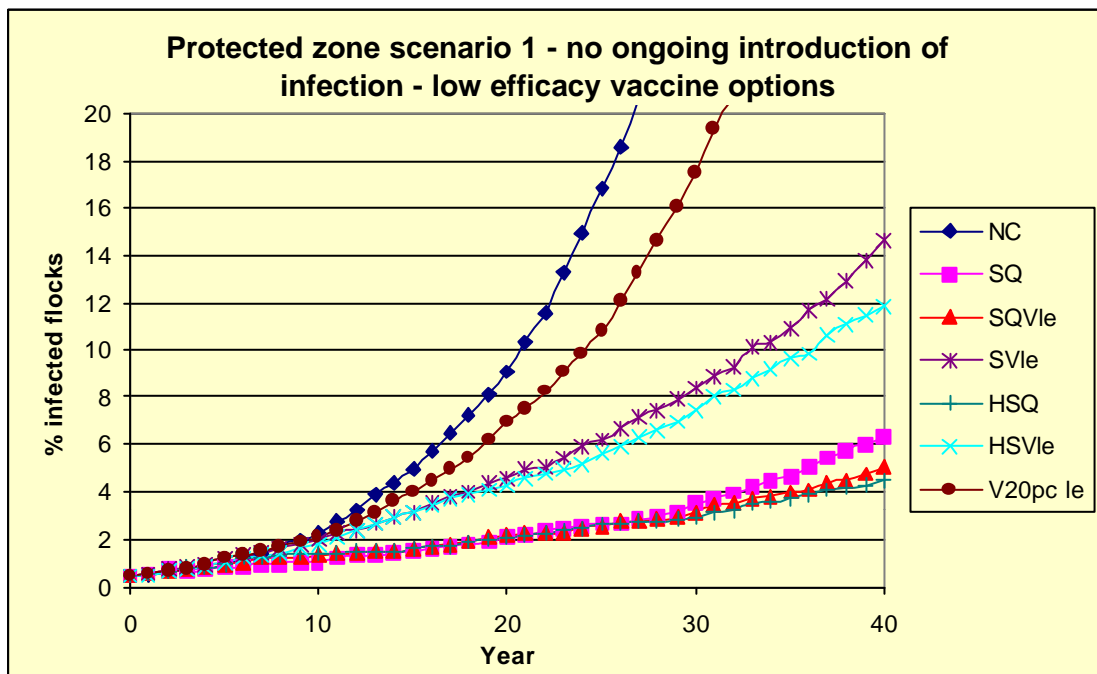


Figure 6: Mean flock-prevalence for Protected Zone scenarios, assuming a 0.5% flock-prevalence at the start, no ongoing introductions of infection, a 40-year simulation period and a low-efficacy vaccine.



5.2.2 Continuing introduction of infection

The assumptions for the second Protected Zone simulation were as for the first simulation, except that it was assumed that there were continuing importations of OJD, with 5% of flocks purchasing replacement sheep from a region with a flock-prevalence of 2%. The same scenarios were run as for the previous simulation, except that ring vaccination was also included (see below).

Results for the second Protected Zone simulation are summarised in Figures 7, 8 and 9. Flock-prevalence increased rapidly under the NC scenario, reaching 71% after 40 years. The SQ, HSQ and V scenarios all provided limited control, with flock-prevalence increasing to 17 – 27% after 40 years. All other scenarios considered (assuming a moderate vaccine efficacy) provided a moderate level of control, with flock-prevalence about 8 – 10% after 40 years. If vaccine efficacy was assumed to be low, flock prevalence under all vaccination strategies increased much more rapidly, reaching 58%, 36% and 33% for the Vle, Svlle and HSVle simulations, respectively. Again, quarantine of detected infected flocks made little difference to final flock-prevalence if vaccine was assumed to be moderately effective, but provided a much higher level of control when combined with vaccination if vaccination efficacy was assumed to be low. Ring vaccination (with or without quarantine of detected infected flocks) provided a slight decrease in flock-prevalence compared to the corresponding strategy without ring vaccination, assuming a moderate-efficacy vaccine.

Figure 7: Mean flock-prevalence for Protected Zone scenarios, assuming a 0.5% flock-prevalence at the start, 5% of flocks introducing sheep from an area with a flock-prevalence of 2%, a 40-year simulation period and a moderate-efficacy vaccine.

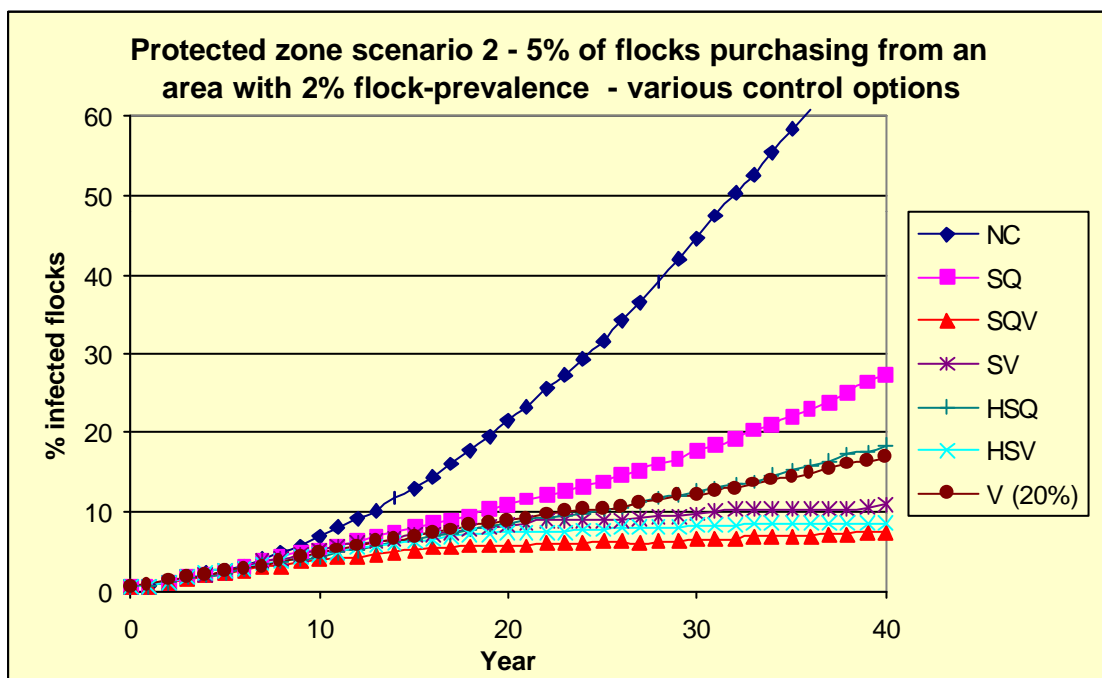


Figure 8: Mean flock-prevalence for Protected Zone scenarios, assuming a 0.5% flock-prevalence at the start, 5% of flocks introducing sheep from an area with a flock-prevalence of 2%, a 40-year simulation period and a low-efficacy vaccine.

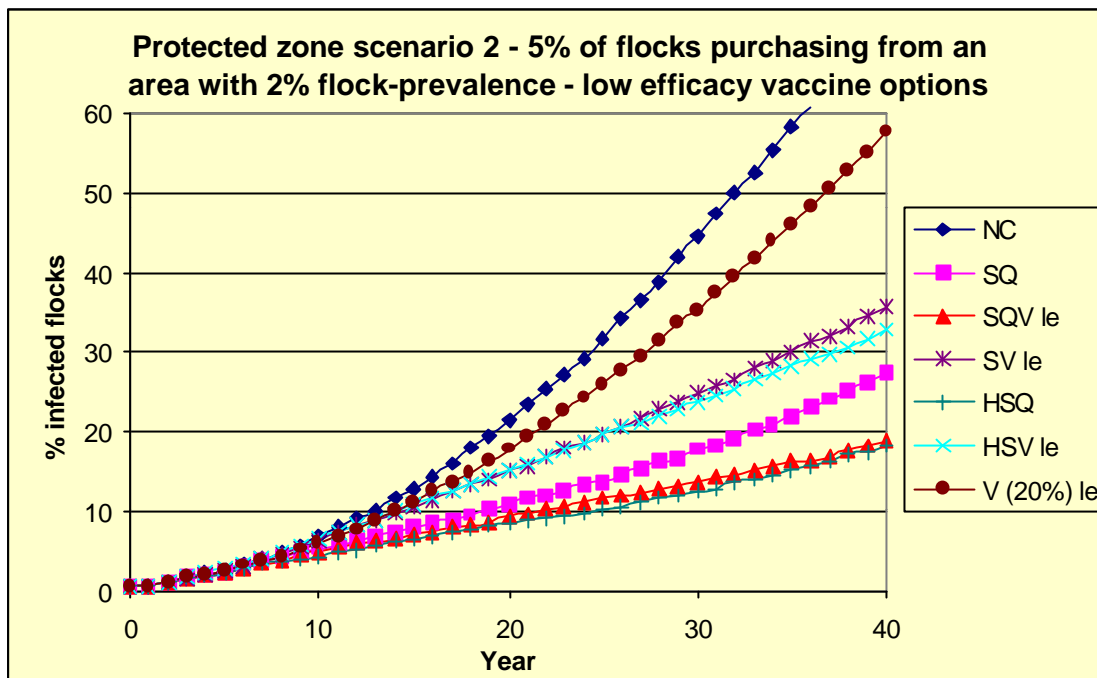
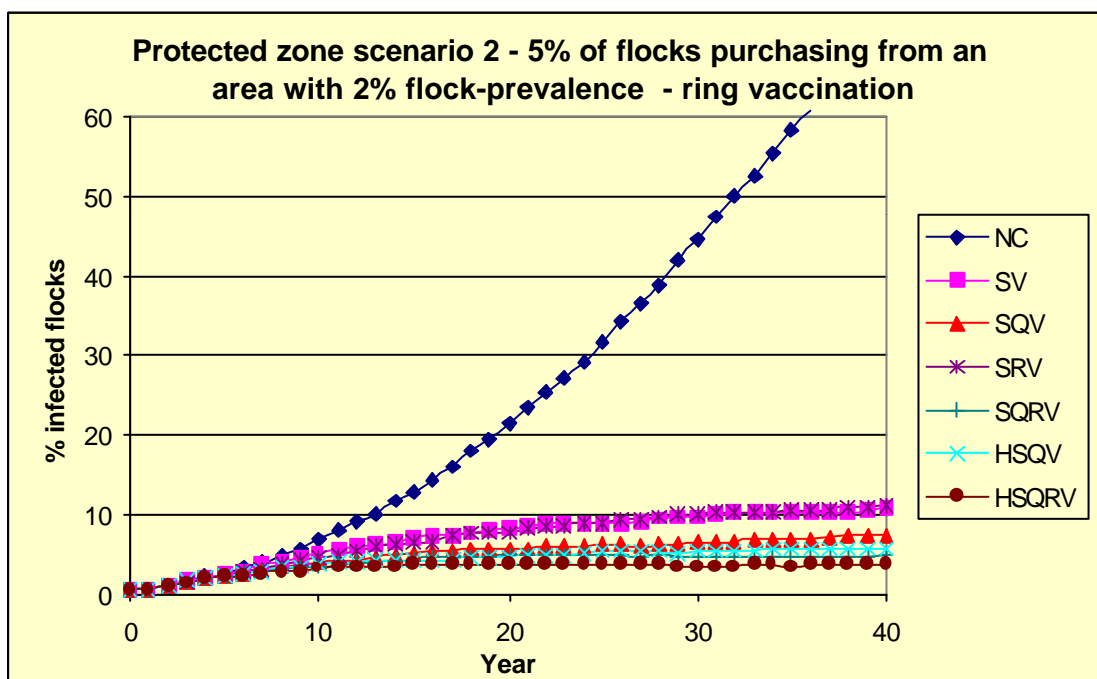


Figure 9: Mean flock-prevalence for Protected Zone scenarios, assuming a 0.5% flock-prevalence at the start, 5% of flocks introducing sheep from an area with a flock-prevalence of 2%, a 40-year simulation period and a moderate-efficacy vaccine, including ring vaccination of detected infected flocks.



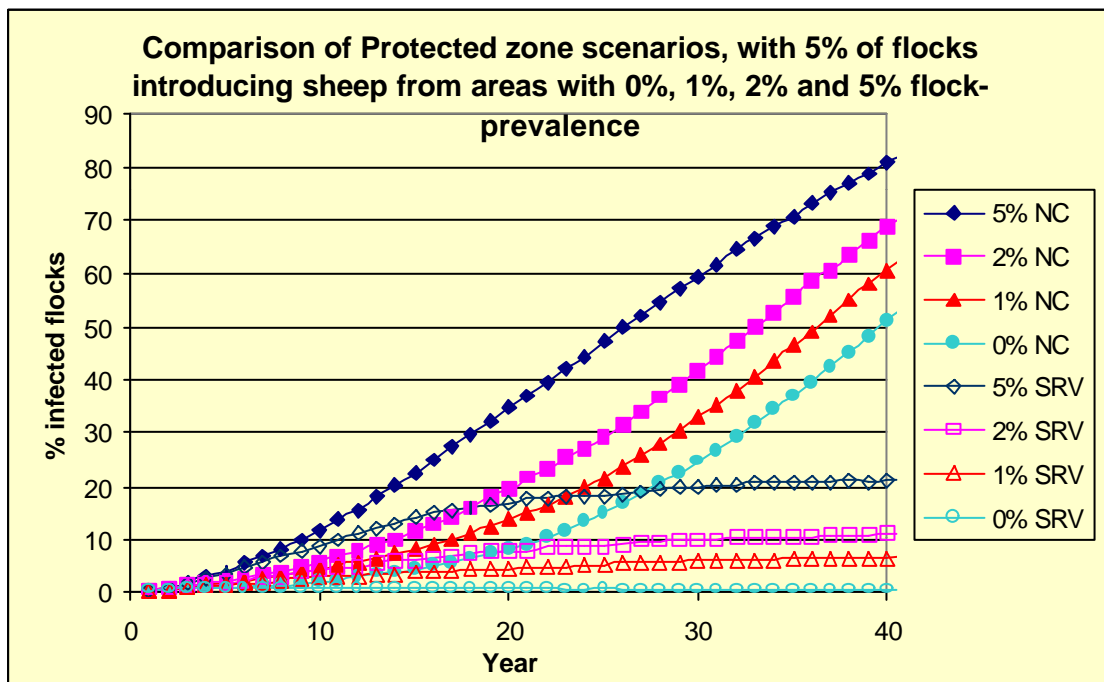
5.2.3 Effect of level of ongoing introduction of infection in Protected Zones

Additional simulations were run assuming that 5% of flocks introduced sheep from areas with 1% and 5% flock-prevalence. Scenarios were run assuming no control measures within the zone and for surveillance and ring vaccination (without quarantine of detected flocks). Other assumptions were as for the previous Protected Zone simulations. The results of a comparison of these scenarios with the comparable scenarios from the previous Protected Zone simulations are summarised in Figure 10.

In practice, the implementation of (voluntary or compulsory) restrictions on movements into a zone results in an effective reduction in the flock-prevalence in the population of flocks from which the introductions are sourced. Therefore, the reduction in flock-prevalence in the source area for the various flock-prevalence levels reflects the effectiveness (uptake) of movement restrictions or risk-based trading for producers purchasing from outside the region. For example, if producers are purchasing from a Control Zone area with a 5% flock-prevalence, the various flock-prevalence levels simulated represent a range in effectiveness of movement restrictions or risk-management from completely effective (0%) to completely ineffective (5%).

For these scenarios, the SRV lines will move up or down depending on the level and effectiveness of surveillance. The lines will also move down if quarantine is used in addition to ring vaccination. Because there are no restrictions on movements within the zone under these scenarios, introduction of risk-based trading or other measures within the zone will result in even better control than shown here. As the flock-prevalence for introduced sheep increases the level and effectiveness of surveillance also becomes more important in maintaining effective control (results not shown)

Figure 10: Comparison of Protected Zone scenarios for 5% of flocks introducing sheep from areas with 0%, 1%, 2% and 5% flock-prevalence, for no control (NC) and ring vaccination without quarantine (SRV) scenarios



5.3 Discussion

From these results, the proposed management plan for the Residual Zone, based on widespread vaccination, trading only in vaccinated sheep and without quarantine of infected flocks, is likely to provide a reasonable level of control of the disease, particularly if vaccine uptake is high. If vaccine efficacy is poor, or if the restriction of purchases to vaccinates-only is ignored, this approach is still likely to limit the further spread of the disease and reduce losses in infected flocks that vaccinate. Even if vaccine uptake is as low as 50% a reasonable reduction in flock-prevalence is likely to be achieved (20% flock-prevalence after 20 years – results not shown). Quarantine without vaccination would result in continued spread, although quarantine plus vaccination would result in some reduction in flock-prevalence, assuming a moderate vaccine efficacy.

For the Protected Zones, a comparison of scenarios 1 and 2 demonstrates the obvious importance of limiting the ongoing introduction of infection into the zone. However, although this is important, it is equally important to implement effective action to limit spread within the zone, as shown in PZ scenario one (Figure 5). In the very early stages of infection, even a moderate level of surveillance plus vaccination of detected infected flocks (with or without quarantine) will provide a reasonable level of control.

For the Protected Zone, as was the case in the Residual Zone, vaccination of infected flocks provides more effective control than quarantine alone, while vaccination plus quarantine and ring vaccination (with or without quarantine) provided the highest level of control for the scenarios considered. For the Protected Zone, targeted vaccination of detected infected flocks (\pm quarantine) provides substantially better control than random vaccination, unless the level of vaccination is quite high (20% to provide similar control to surveillance plus quarantine, 50% to provide similar control to surveillance plus vaccination – results not shown). This is probably a higher level of vaccination than can be economically justified or practically achieved in a low-prevalence region.

A very important consideration in any regional control program is vaccine efficacy. The modelling clearly shows that reliance on vaccination will result in considerably less-effective control if vaccine efficacy is low. Under these circumstances, quarantine becomes much more important. Despite this, surveillance and quarantine without vaccination will provide only limited control, at best. Therefore, vaccination must be an important part of any control program, even if its efficacy is lower than has been hoped, or has been modelled in these simulations. The role of quarantine in providing additional control is also likely to be determined by other issues, such as the development of risk-based trading options and industry attitudes to continued use of quarantine as a control measure, as well as about likely vaccine efficacy.

Because of the nature of the model, and the complexity of possible trading options, it has not been possible to model the proposed risk-based approach to sheep-trading in this analysis. However, the scenarios analysed provide an indication of the likely effect of various strategies in the absence of any restrictions on movement within and between zones, other than quarantine of detected infected flocks, where appropriate. Therefore, imposition of risk-based trading on top of these options should only improve the level of control achieved, with the magnitude of the improvement depending on the level of uptake of risk-based trading. In addition, Figure 10 shows the potential effect of risk-based trading

when applied to introductions from a higher-risk zone, so that the better the uptake of risk-based trading or the more effective inter-zone movement restrictions, the higher the level of control that will be achieved.

6 Risk-based trading options

Although the simulation analysis reported above considers the Residual and Protected Zones independently, this is not truly the case, particularly if risk-based trading is to be implemented. Therefore, rather than considering options for the implementation of risk-based trading in the individual zones, it is more appropriate to consider options for implementation in an integrated fashion across all zones, so that risk-based trading provides a basis for management of risk associated with sheep movements both within and between zones.

To assist in consideration of options for the implementation of risk-based trading, four options have been considered in some detail, with a summary of the strengths and weaknesses of each option presented in Table 6. Briefly, the options considered were:

1. Implementation under the existing regulatory framework;
2. Implementation with partial de-regulation;
3. Implementation as a voluntary system with no regulatory support other than to provide a legal basis for vendor declarations; and
4. Complete de-regulation.

In summary, implementation of risk-based trading under the existing regulatory framework is unlikely to be acceptable to large numbers of affected producers caught in the regulatory or zoning nets, and will still not necessarily achieve a high level of control. At the opposite end of the spectrum, complete de-regulation will allow unrestricted spread of the infection, without providing any means for those wishing to protect their flocks to do so. Therefore, one of the intermediate options of a voluntary system, possibly with some level of regulatory support appears to be the most realistic option. These options provide producers with incentives to take positive action to protect themselves, or to control the disease if their flock is already infected. At the same time, these will reduce the ongoing spread of the disease below what would otherwise be the case, with the level of control achieved being determined by the importance that producers are prepared to place on OJD and their consequent level of adoption of the scheme.

Table 6. Comparison of four possible risk-management strategies for OJD in the Australian sheep industry.

Strategy	Description	Strengths	Weaknesses
Continued regulation (status quo)	<ul style="list-style-type: none"> • Quarantine of infected flocks (or zone quarantine for management area) • Continued MAP, abattoir surveillance and tracing • Inter-zone (and intra-zone?) sheep movements regulated • Trading options limited by regulatory action • Vaccine use controlled 	<ul style="list-style-type: none"> • Potentially high level of protection of unaffected producers in control and protected zones if implemented effectively 	<ul style="list-style-type: none"> • High level of resources required • Producer resistance likely • Financial assistance for affected producers critical for success • Difficult to effectively police movement restrictions • Spread will continue despite control measures
Partial de-regulation, industry-based program	<ul style="list-style-type: none"> • Quarantine infected flocks only • Vaccine freely available • Infected flocks and neighbours permitted to trade vaccinates only • Continuing abattoir surveillance • Mandatory vendor declaration for sheep sales to include OJD risk-score • No restrictions on trade within and between zones • Promotion of risk-score as basis for purchasing decisions 	<ul style="list-style-type: none"> • Continued regulation of high-risk flocks • Provides a basis for unaffected producers to protect themselves • Encourages affected producers to take positive steps to control the disease • Reduced regulatory impact on affected producers 	<ul style="list-style-type: none"> • Continued significant cost to industry/governments • Maintenance of surveillance and zones necessary for risk-management • Spread will continue despite control measures • Continuing regulation may be resisted by some sections of industry • Partial deregulation may be opposed by some States/industries • State-level restrictions may be imposed if not all States support the changes • Considerable education of producers will be necessary for the approach to be understood and effectively implemented • Limited protection for risk-averse producers from less risk-averse neighbours

<p>Vaccination and risk-management, with minimal regulation</p>	<ul style="list-style-type: none"> • No quarantine or other regulatory activity • Vaccine freely available • Abattoir surveillance and zones maintained as risk-management tools • Mandatory (or voluntary?) vendor declaration for sheep sales to include OJD risk-score • No restrictions on trade within and between zones • Promotion of risk-score as basis for purchasing decisions 	<ul style="list-style-type: none"> • Any impact on affected producers determined by the free market, rather than regulation • Provides a basis for unaffected producers to protect themselves • Encourages affected producers to take positive steps to control the disease • Allows market forces and producer attitudes to risk to determine disease spread 	<ul style="list-style-type: none"> • Continued cost to industry for surveillance, vendor declarations and risk-management activities • Maintenance of surveillance and zones necessary for risk-management • Spread will continue despite measures • Likely to be opposed by some States and/or industries • State-level restrictions may be imposed if not all States support the changes • Considerable education of producers will be necessary for the approach to be understood and effectively implemented • Limited protection for risk-averse producers from less risk-averse neighbours
<p>De-regulation</p>	<ul style="list-style-type: none"> • Complete de-regulation • Abattoir surveillance and zoning discontinued • MAP retained on voluntary basis • No other risk-management measures supported 	<ul style="list-style-type: none"> • Low-cost in terms of 'industry-level' disease control • No trade restrictions on affected producers or regions (subject to National agreement) 	<ul style="list-style-type: none"> • Unrestricted spread of OJD will resume • Very difficult for producers to protect themselves from OJD • Potentially very high cost in terms of on-farm disease and control costs over the longer term • Likely to be strongly opposed by States and some producers in the Protected Zone • State-level restrictions may be imposed if not all States deregulate

7 Conclusion

The system for risk-based classification of flocks proposed here has an intuitive appeal for further development and application in the NOJDP and any future national OJD program. The proposed system has the advantages of being both relatively simple and easy to understand, but at the same time is supported by its scientific basis. Because precise quantitative estimates of risk were not required, it was possible to convert the results of the detailed analysis to a simple numerical scale for each flock, greatly simplifying the resulting *risk-score*.

The main disadvantages are that many of the parameters used in developing a risk profile for any flock are still unknown, and so estimates must be based on expert opinion. Similarly, some of the assumptions on which the methodology has been based may not be valid, resulting in bias of the resulting risk-estimates. However, compared to the alternative of either rigorous risk assessments based on individual circumstances or a totally qualitative assessment of risks, this approach was felt to provide a reasonable compromise, resulting in reasonable risk estimates that could be easily understood and interpreted by producers and their advisers.

Simulation modelling was also used to evaluate the potential effectiveness of various control measures within Residual and Protected Zones. For the Residual Zone a high coverage with vaccination was essential for effective control, with movement restrictions providing additional benefit if vaccination coverage was <100%. For the Protected Zone, a reduction in the level of ongoing introduction of infection from other zones and effective surveillance for early identification and vaccination of infected flocks are essential for effective control. Ring vaccination and/or quarantine of infected flocks would provide added control.

Although this approach provides a simple framework on which to base a risk-based trading system, it was beyond the scope of this project to develop a detailed system for implementation. Before this can happen it is essential to achieve national agreement on a suitable model for implementation, as well as on the most appropriate input values for the risk-model, methods for re-scaling of model output and to the final *risk-scores* for each flock type and risk/mitigating factor. The ongoing validity of this approach will also depend on continuing availability of surveillance and other data to maintain the credibility of the proposed flock-categorisation.

8 References

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- Sergeant ESG, in press. Estimated prevalence and distribution of ovine Johne's disease in Australia at 31 December 2001. *Aust. Vet. J.*
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Appendix 1. Paper submitted and accepted for publication in the Australian Veterinary Journal

Estimated flock-prevalence and distribution of ovine Johne's disease in Australia at December 2001

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As part of the National Ovine Johne's Disease Control and Evaluation Program, the flock-prevalence and distribution of ovine Johne's disease (OJD) in Australia at the end of December 2000 were recently estimated using data from abattoir surveillance and other sources.¹ A Bayesian method was used to adjust for the imperfect sensitivity of abattoir surveillance and for uncertainty about sensitivity and assumed flock-prevalence in each State and region.

This report updates the previous estimates of OJD flock-prevalence by State, and by region within New South Wales. The same method as for the previous analysis was used, with flock-prevalence estimates updated to take into account the results of abattoir surveillance undertaken during 2001.

For the current analysis, the same prior distributions for the sensitivity and specificity of abattoir surveillance were used as for the previous analysis for each State or region. α and β parameters for prior distributions for flock-prevalence were estimated by trial-and-error, to provide distributions that closely approximated the median and 97.5th percentile of the output distributions for flock-prevalence from the previous analysis. The results of abattoir surveillance for the 12 months to 31 December 2001 for each State or region were used as inputs. A Gibbs sampler was used to combine the prior flock-prevalence, sensitivity and specificity estimates with the observed results of abattoir surveillance, to produce probability distributions of flock-prevalence for each State and region. Estimates are presented as median and 95% probability intervals from the probability distributions.

For the analysis of New South Wales' data, the State was divided into three regions according to apparent prevalence of known infected flocks (at 31 December 2000) by Rural Lands Protection Board as follows:

High Prevalence (HP): >5% of flocks infected – Central Tablelands and Goulburn RLPB districts

Moderate Prevalence (MP): 0.5 – 5% of flocks infected - Wagga Wagga, Murray, Forbes, Cooma, Gundagai, Hume, Young, Braidwood, Molong and Yass RLPB districts

Low Prevalence (LP): <0.5% of flocks infected – Remaining RLPB districts

For other States, prevalence was estimated for the entire State, except for Tasmania, where data for Flinders Island were excluded from the analysis

The results of this analysis are summarised in Table A1. For Queensland, South Australia, Tasmania and Western Australia the estimated prevalence remained virtually unchanged. Median prevalence estimates in Victoria and the three regions of New South Wales have all increased

slightly from the 2000 estimates. This is associated with an increased proportion of lines from these areas that were positive in 2001 compared to 2000. These increases might reflect a real increase in the underlying prevalence due to ongoing spread of infection, or may be due to normal sampling variation and the effect of biases inherent in using abattoir surveillance as a tool to estimate flock-prevalence.

The estimates of flock-prevalence presented here are subject to a number of potential biases.¹ Briefly, the estimates may be affected by the non-representative nature of abattoir surveillance as a sampling procedure for the population of interest, as well as by uncertainty about the true flock-sensitivity of abattoir surveillance and of prior estimates of flock-prevalence.

Because of the potential for bias, the estimates presented here must be regarded as approximate, rather than highly precise estimates of flock-prevalence. Despite this, these estimates provide the best available indicators of prevalence and distribution at this time. Importantly, the apparent distribution of OJD in Australia has remained largely unchanged after an additional 12 months and 20,000 lines of sheep subjected to abattoir surveillance. Therefore, although there may be some additional infected flocks still undetected in the low prevalence areas, there are unlikely to be major foci of infection still undetected.

Ongoing surveillance will allow these estimates to be further refined as more data becomes available. However, particularly in the lower prevalence regions, estimates are unlikely to change substantially without improved certainty about the true sensitivity of abattoir surveillance in these areas, even with large increases in the amount of surveillance undertaken.

Acknowledgments

This study was commissioned by Animal Health Australia as part of the National Ovine Johne's Disease Control and Evaluation Program, using data provided by State authorities.

References

1. Sergeant ESG, Baldock FC. The estimated prevalence of Johne's disease infected sheep flocks in Australia. *Aust Vet J* in press;

Table A1. Estimated flock-prevalence of ovine Johne's disease in six States of Australia at 31 December 2000, plus abattoir surveillance results and updated flock-prevalence estimates to 31 December 2001

State/Region	Estimated prevalence, December 2000		Abattoir surveillance results for 2001			Updated prevalence, December 2001	
	Median	95% Interval	Lines tested	Lines +ve	% +ve	Median	95% Interval
NSW – HP ^a	33	29 - 39	1137	403	35	38	34 - 43
NSW – MP ^b	11	8 - 15	3760	343	9	15	12 - 19
NSW – LP ^c	0.5	0.05 - 1.5	4704	23	0.5	0.8	0.1 - 1.7
Qld	0.3	< 1.0	1045	0	0.0	0.2	< 0.5
SA ^d	0.15	0.03 - 0.5	3538	3	0.1	0.2	0 - 0.4
Tas ^e	0.4	0.05 - 1.1	260	0	0.0	0.3	0.1 - 0.9
Vic	0.4	0.05 - 1.1	5143	54	1.0	1.8	0.1 - 3.5
WA	0.2	< 0.8	566	0	0.0	0.2	< 0.6

^a HP: >5% of flocks confirmed infected – Central Tablelands and Goulburn Rural Lands Protection Board districts

^b MP: 0.5 – 5% of flocks confirmed infected – Wagga Wagga, Murray, Forbes, Cooma, Gundagai, Hume, Young, Braidwood, Molong and Yass districts

^c LP): <0.5% of flocks confirmed infected – 29 remaining Rural Lands Protection Board districts of New South Wales

^d Data for Kangaroo Island were excluded from prevalence estimate at December 2000

^e Data for Flinders Island were excluded from prevalence estimates December 2000 and December 2001

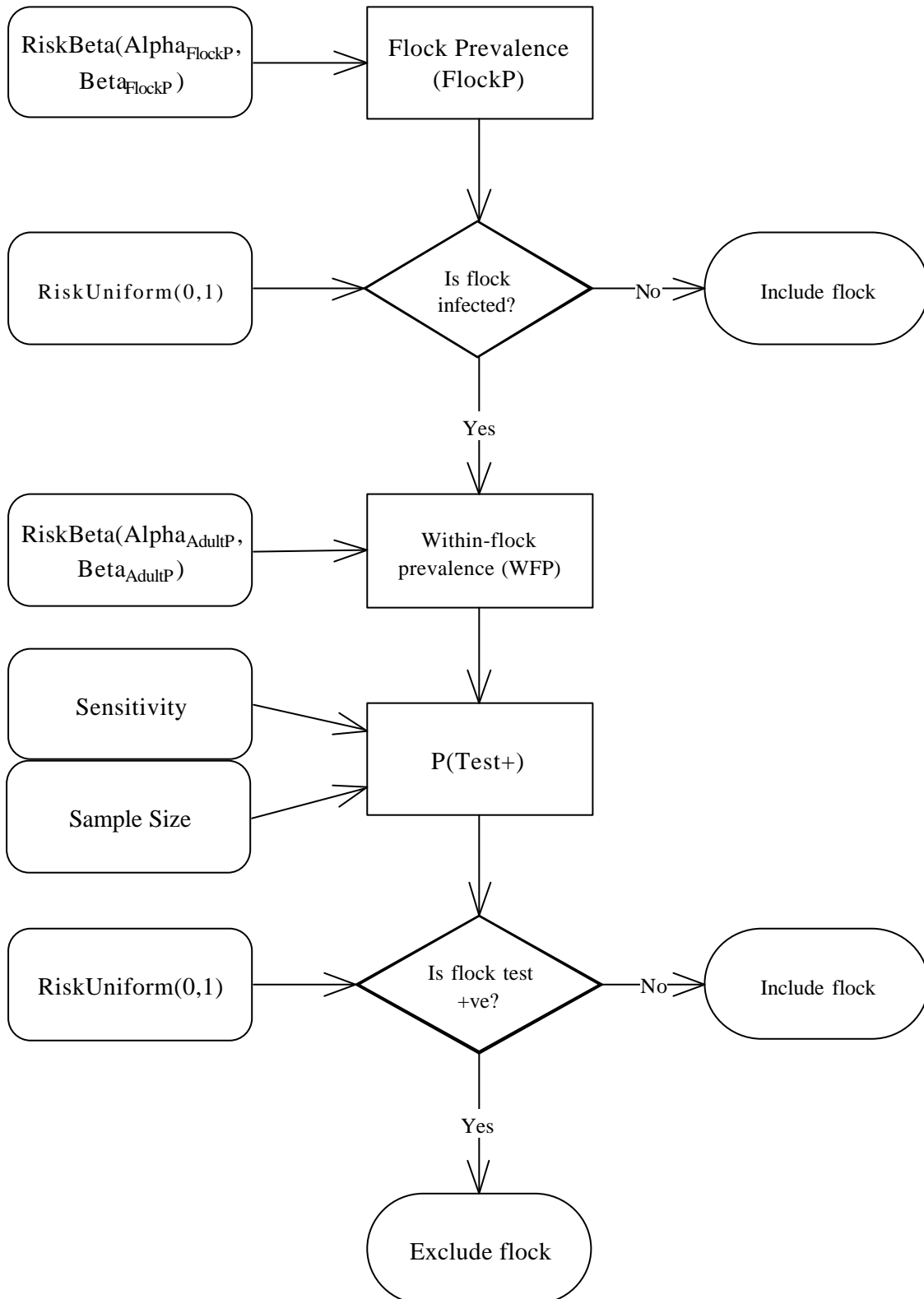
Appendix 2. Methodology for estimating the effect of negative abattoir surveillance on FP and WFP

A simulation model developed in @Risk and Excel was used to estimate FP and WFP for flocks with varying levels of abattoir surveillance. Simulations were repeated for each of the Residual, Control and Protected zones, and for sample sizes of 250, 750 and 1100, corresponding to abattoir surveillance categories of 50-500, 501-1000 and >1000 respectively. For each simulation, inputs were FP and WFP for unrestricted flocks in the respective zone, test sensitivity and sample size. For the Protected Zone, a weighted-average prevalence was used to estimate FP (mode = 1%, upper 95% = 2%). For other zones and for WFP for all zones the values from Table 2 were used. For each simulation, the model simulated whether or not the flock was infected, the prevalence in adult sheep and the result of testing the flock, as shown in Figure A1. Each simulation was run for 50,000 iterations to ensure that there were a reasonable number of infected flocks that escaped detection.

Relative risk values for FP were then calculated as follows:

- FP for each simulation was the proportion of test-negative iterations that were infected;
- WFP was estimated as the mean within-flock prevalence for the test-negative but infected flocks;
- Relative risks were calculated for each zone, sample size and for FP and WFP as the ratio of the mean of the unrestricted prevalence value (FP or WFP) to the corresponding estimate from the simulation;
- For both FP and WFP, the lowest (middle, highest) of the relative risk estimates for each sample size was used as the minimum (mode, maximum) value for the corresponding abattoir surveillance category;

Figure A1. Flow chart for simulation model to estimate FP and WFP for various levels of negative abattoir surveillance



Appendix 3. Effect of age and vaccination on OJD infection-prevalence

Simulation modelling was used to investigate the relationship between prevalence of *M. paratuberculosis* infection in adults and hoggets in the same flock and between unvaccinated adults and vaccinated adults and hoggets under the same conditions. A stochastic simulation model was used to estimate infection-prevalence (Sergeant, 2002a; Sergeant, 2002b), with input parameters specified that resulted in a median annual mortality rate in adults of 12% per year (95% interval: 10.5 – 13.5%). The model was run for two scenarios, both for a simulated 30-year period for an assumed self-replacing flock of 2,000 ewes, with 4 infected animals in year 0. The first scenario assumed that no control measures were implemented, while the second assumed that annual vaccination of lambs commenced in year 20 and continued until the end of the simulation period. The vaccination scenario assumed a moderate vaccine efficacy, with 60% of susceptible vaccinates becoming resistant to infection and a 40% reduction in the rate of progression of latent infections in vaccinated animals. These assumed values produce simulation results that are consistent with the observed effect of vaccination in the current vaccination trial in New South Wales. For each scenario, the proportions of infected adults and hoggets were calculated at the end of each simulated year, and are graphed in Figure A2. The ratios between adult prevalence and prevalence in unvaccinated hoggets, vaccinated adults and vaccinated hoggets are shown in Figure A3.

The modelling results suggest that the prevalence of infection in hoggets averages about 1.8 times that of adult sheep in the same flock (range: 1.6 – 2.5) (See Figures A2 and A3). The ratio is higher in more recently infected flocks and declines over time. Similarly, prevalence in vaccinated adults (and hoggets) ranges from 0.2 to 0.7 times the prevalence in comparable non-vaccinated adults in the period from 2 – 6 years after commencing vaccination and is <0.2 times prevalence in non-vaccinates for flocks vaccinating for >6 years (Figures A2 and A3).

Figure A1. Simulated median prevalence of OJD infection in hoggets and adults with and without vaccination, with vaccination commencing in year 20.

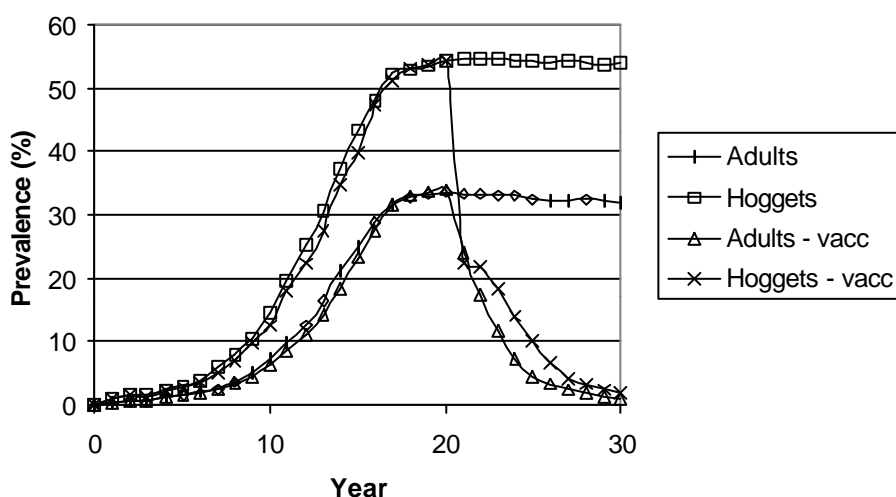


Figure 4. Ratio of simulated median prevalence in hoggets, vaccinated adults and vaccinated hoggets to prevalence in non-vaccinated adults, with vaccination commencing in year 20.

